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EXAMINER

YU, GINA C

ART UNIT

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1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of No. 3:

The proposed amendment to limit the crosslinked hydrophilic polymers to in-situ type requires a new search and consideration and a new rejection if necessary. Applicant's reference to MPEP 904.02 that initial examination should cover "the disclosed features which might reasonably be expected to be claimed" is noted. However, in this case, although in-situ polymers are disclosed in the specification, applicant had chosen to not to claim such limitation in the previous prosecution. The examiner could not have reasonably expected or foreseen applicant's own action. The search and examination during the previous prosecution did not take into consideration how applicant would amend the claims to limit the crosslinked polymers to in-situ polymers. Although a thorough search and examination have been conducted with respect to the applicant's original and previously presented claims which did not require the polymers be in-situ polymers, the currently submitted proposed amendment containing a new limitation will need a new search and consideration.

Continuation of No. 11:

Applicant's arguments based on proposed amendment are not considered to due the non-entry of the amendment.

In the remaining portion of the remarks, applicant argues that the cited references individually fail to teach or suggest every limitation of the claims in within each of the single reference. Applicant is respectfully reminded that the rejections of record is not made under 35 U.S.C. § 102. In response to applicant's arguments

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against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on **combinations of references**.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Becher already teaches a dosage form in film using a crosslinked hydrophilic polymer. The modification of the amount of glycerol or substituting the crosslinked polymer with another art-recognized film-forming polymer would have been a prima facie obviousness matter, as indicated in the rejection. Although the cited references are directed to inventions of different features, all are in pharmaceutical art and available to one of ordinary skill in the art, and there is no reason why a skilled artisan would have been deterred from combining the teachings of these references.

With respect to the rejection based on the obviousness of optimization of the glycerol amount, applicant asserts no result-effective variable has been recognized by the office. However, examiner already indicated in the rejection that glycerol is used as a plasticizer, i.e., a softener for the film. Production of the film with suitable softness is the result-effective variable indicated in the rejection. It would have been plainly obvious to a skilled artisan to modify the amount of glycerol to adjust the plasticity, i.e., the softness of the film to the desired degree. Applicant is respectfully reminded that *In re Aller* is the precedent in patent law in this case, and a mere manipulation of a concentration for a known result is not a patentable matter. See 200 F.2d 454, 456, 105 U.S.P.Q. 233, 235 (C.C.P.A. 1955).

While applicant asserts that a plasticizer are normally employed only up to 20 wt % due to a possible crystallization, there is no evidence to support the statement. See In re Schelze, 346 F.2d 600, 602, 145 U.S.P.Q. 716, 718 (C.C.P.A. 1965), which holds that an attorney's arguments cannot take the place of evidence.

Without making any reference to specific documents, applicant asserts unexpected results are made of record, although it appears applicant is referring to the disclosure made on specification p. 23-25. Assuming this is the alleged evidence of expected result, examiner maintains the position that the disclosure only shows glycerol is a better plasticizer over other polyols. Such showing does not amount to an unexpected result, when prior arts have already shown the specific utility of glycerol as a preferred plasticizer for film forming polymers in pharmaceutical art.

The obviousness rejections of record are viewed proper, and applicant's arguments are unpersuasive to overcome the rejections. Applicant's alleged evidence of unexpected results do not show unexpected or surprising results of using glycerol as a plasticizer for film forming polymers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1611